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INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year)

03.07.2000

Applicant's or agent's file reference
16336-001010PC

IMPORTANT NOTIFICATION

International application No.
PCT/US99/19434 ✓

International filing date (day/month/year)
30/08/1999 ✓

Priority date (day/month/year)
31/08/1998 ✓

Applicant

UNIVERSITY OF WASHINGTON et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

2-28-01

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16336-001010PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/19434	International filing date (day/month/year) 30/08/1999	Priority date (day/month/year) 31/08/1998
International Patent Classification (IPC) or national classification and IPC G01N33/58		
Applicant UNIVERSITY OF WASHINGTON et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25/01/2000	Date of completion of this report 03.07.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Thiele, U Telephone No. +49 89 2399 8643



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/19434

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-36 as originally filed

Claims, No.:

1-30 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US99/19434

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 7,12,13,24-30
	No: Claims 1-6,8-11,14-23
Inventive step (IS)	Yes: Claims
	No: Claims 1-30
Industrial applicability (IA)	Yes: Claims 1-30
	No: Claims

2. Citations and explanations

see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Section V

- 1) Reference is made to the following documents:

D1: US-A-5 338 686

D2: WO 98 36095 A

D3: DE 44 33 384 A

D4: US-A-5 910 403

- 2) The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1 and 18, and claims 2 - 6, 8 - 11, 14 - 17 and 19 - 23 as dependent thereon is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

- a) D1 discloses the basic concepts according to present claims 1 and 18 of determining the mass isotope enrichment of a subunit from which a biopolymer is formed, and the rates of synthesis and decay of the biopolymer (see col. 2, lines 5 - 7, lines 20 - 38; col. 3, lines 9 - 12; col. 4, line 47; Table 1; chapters III and IV; claims 1 - 9). The methods include administering the isotopically labelled subunits into human subjects.

Moreover, D1 would appear to relate to the particular technical features of present claims 1 - 5, 8, 15 - 17 and 19 - 23 (see loc. cit.).

- b) D2 pertains to an assay for the measurement of DNA synthesis rates which relies on the use of nonradioactive tracer technology. The assays are done in cell culture. Prior to analysis, the biopolymer is separated and fragmented (see page 1, paragraph 1; page 6, line 27 - page 9; pages 11 - 14; pages 37 - 41; claims).

Thus, D2 is prejudicial to the novelty of claims 1 - 6, 8 - 11 and 14 - 17.

- c) D3 discloses toxicological test to determine particular external effects on protein synthesis in living material, namely cells, comprising incubating the living material with a ^{15}N -labelled nitrogen source under standardised conditions for a fixed time and measuring the relative abundance of ^{15}N by isotope analysis of

the living material or a protein fraction thereof.

Consequently, D3 is prejudicial to the novelty of claims 1 - 6.

- 3) Dependent claims 7, 12, 13 and 24 - 30 do not appear to contain any additional features which, in combination with the feature of the claim(s) to which they refer, involve an inventive step (Art. 33(3) PCT).

The said features would appear to be purely conventional, and the advantages resulting therefrom readily foreseeable.

Section VI

The intermediate document D4 (publication date: 08.06.99; filing date: 15.05.97) would appear to disclose or make obvious the subject-matter of claims 1 - 30.

However, it is assumed that the priority of the present application is validly claimed. The present priority date of 31.08.98 is, namely, before the publication date of D4.

Section VII

- 1) The statement on page 1, first paragraph has no bearing on the invention or its background art and thus contravenes, as being irrelevant, Art. 6 and Rule 9.1(iv) PCT.
- 2) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 - D3 is not mentioned in the description, nor are these documents identified therein.
- 3) The sequence ID Nos have been omitted from page 36.